June 1, 2018

SysMed (China) Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K172234
Trade/Device Name: Oxygen Concentrator, Models M30, M40, and M50
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: April 26, 2018
Received: April 30, 2018

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172234

Device Name
Oxygen Concentrator
Models M30, M40, and M50

Indications for Use *(Describe)*
The Oxygen Concentrator is intended for the administration of supplemental oxygen. This device is not intended for life supporting nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel, at home, in community health care and medical institutions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172234

1. Date of Preparation: 05/31/2018

2. Sponsor Identification

SysMed (China) Co., Ltd
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3. Designated Submission Correspondent Ms.

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4. Identification of Proposed Device

Trade Name: Oxygen Concentrator
Common Name: Portable Oxygen Generator
Models: M30, M40, M50

Regulatory Information
Classification Name: Generator, Oxygen, Portable
Classification: 2
Product Code: CAW
Regulation Number: 21CFR 868.5440
Review Panel: Anesthesiology

Intended Use Statement:
The Oxygen Concentrator is intended for the administration of supplemental oxygen. This device is not intended for life supporting nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel, at home, in community health care and medical institutions.

Device Description
The Oxygen Concentrator adopts the principle of pressure swing adsorption technology. At normal temperature, the device can continuously supply a high concentration of supplemental oxygen (93%±3%).

The main function of the proposed device includes supplying supplemental oxygen. The device also includes alarms for high temperature, low oxygen output, and interruption of power.

The proposed device includes three models, which are M50, M40 and M30. The only difference of the three models is flow rate.

5. Identification of Predicate Devices

510(k) Number: K150930
Product Name: Deployable Oxygen Generator System - Small (DOGS-S)

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ISO 80601-2-69 First Edition 2014-07-15, Medical Electrical Equipment - Part 2-69: Particular Requirements For Basic Safety And Essential Performance Of Oxygen Concentrator Equipment.
- ISO 10993-5:2009, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
- VOCs and PM2.5 test per EPA TO 15 and IP-10 method

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device M30, M40, M50	Predicate Device K150930
Classification	2	2
Product Code	CAW	CAW
Regulation Number	21 CFR 868.5440	21 CFR 868.5440
Intended Use	The Oxygen Concentrator is intended for the administration of supplemental oxygen. This device is not intended for life supporting nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel, at home, in community health care and medical institutions.	The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. This device is not intended for life support nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel.
Use environment	home, community health care and medical institutions	Home, hospital and medical facility
Operation principle	pressure swing adsorption technology (PSA)	pressure swing adsorption technology (PSA)
Oxygen purity	93% +/- 3%	93% +/- 3%

Flow type	Continuous flow	Continuous flow
Flow rate	M30: 0-3 L/min M40: 0-4 L/min M50: 0-5 L/min	0.5 - 15 L/min
Sound level	≤45 dBA	<70dBA
Oxygen purity warning	<82%	<85%
Electrical requirements	110V/220V, 50Hz/60Hz	110V/240V, 50Hz/60Hz Battery
Outlet pressure	0.05 Mpa ± 10%	10.0 psig

Discussion: The intended use environments of both devices are the same. However, the indications for use of the proposed device identifies the intended use environment while the indications for use of the predicate does not.

The flow rate of proposed device is within that of the predicate device. Although the oxygen purity warning level is less than that of the predicate device, and the outlet pressure of proposed device is 0.05Mp, which is equal to 7.25 psig and less than that of predicate device, both of them comply with the requirements of ISO 80601-2-69. The electrical power requirements of the proposed device is different than that of predicate device, but both of them comply with standards AAMI / ANSI ES60601-1 and IEC 60601-1-2. These differences do not raise different questions of safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device models are Substantially Equivalent (SE) to the predicate devices.